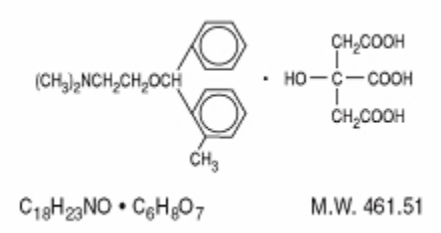
ORPHENADRINE CITRATE EXENDED-RELEASE - orphenadrine citrate tablet
Sandoz Inc.

Rx only

DESCRIPTION
Orphenadrine citrate is the citrate salt of orphenadrine: (2-dimethyl-aminoethyl 2-methylbenzhydryl ether citrate). It occurs as a white, crystalline powder having a bitter taste. It is practically odorless; sparingly soluble in water, slightly soluble in alcohol and has a molecular weight of 461.51. The molecular formula $C_{18}H_{23}NO \cdot C_6H_8O_7$ is represented by the following structural formula:



Each Orphenadrine Citrate Extended-release tablet contains 100 mg orphenadrine citrate. Orphenadrine Citrate Extended-release tablets also contain: calcium stearate, ethylcellulose, and lactose monohydrate.

ACTIONS
The mode of therapeutic action has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate also possesses anticholinergic actions.

INDICATIONS
Orphenadrine citrate is indicated as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute painful musculo skeletal conditions. The mode of action of the drug has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate does not directly relax tense skeletal muscles in man.

CONTRAINDICATIONS
Contraindicated in patients with glaucoma, pyloric or duodenal obstruction, stenosing peptic ulcers, prostatic hypertrophy or obstruction of the bladder neck, cardio-spasm (megaesophagus) and myasthenia gravis.
Contraindicated in patients who have demonstrated a previous hypersensitivity to the drug.

WARNINGS
Some patients may experience transient episodes of lightheadedness, dizziness or syncope. Orphenadrine citrate may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.

PREGNANCY
Pregnancy Category C. Safe use of orphenadrine citrate has not been established with respect to adverse effects upon fetal development. Therefore, orphenadrine citrate should be used in women of childbearing potential and particularly during early pregnancy only when in the judgement of the physician the potential benefits outweigh the possible hazards.

PEDIATRIC USE
Safety and effectiveness in pediatric patients have not been established; therefore, this drug is not recommended for use in the pediatric age group.

PRECAUTIONS
Confusion, anxiety and tremors have been reported in few patients receiving propoxyphene and orphenadrine concomitantly. As these symptoms may be simply due to an additive effect, reduction of dosage and/or discontinuation of one or both agents is recommended in such cases.
Orphenadrine citrate should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency, cardiac arrhythmias.
Safety of continuous long-term therapy with orphenadrine has not been established. Therefore, if orphenadrine is prescribed for prolonged use, periodic monitoring of blood, urine and liver function values is recommended.

ADVERSE REACTIONS
Adverse reactions of orphenadrine are mainly due to the mild anticholinergic action of orphenadrine, and are usually associated with higher dosage. Dryness of the mouth is usually the first adverse effect to appear. When the daily dose is increased, possible adverse effects include tachycardia, palpitation, urinary hesitancy or retention, blurred vision, dilatation of pupils, increased ocular

tension, weakness, nausea, vomiting, headache, dizziness, constipation, drowsiness, hypersensitivity reactions, pruritus, hallucinations, agitation, tremor, gastric irritation, and rarely urticaria and other dermatoses. Infrequently, an elderly patient may experience some degree of mental confusion. These adverse reactions can usually be eliminated by reduction in dosage. Very rare cases of aplastic anemia associated with the use of orphenadrine tablets have been reported. No causal relationship has been established.

DOSAGE AND ADMINISTRATION

Adults-Two tablets per day; one in the morning and one in the evening.

HOW SUPPLIED

Orphenadrine Citrate Extended-release Tablets, 100 mg, white, round-shaped tablets debossed “E” over “22” on one side and plain on the other side are available in bottles of 100 and 1000.

Store at 20°- 25°C (68°-77°F)[See USP Controlled Room Temperature].

Dispense in tight, light-resistant containers as defined in the USP, with a child-resistant closure as required.

KEEP TIGHTLY CLOSED.

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN.

Sandoz Inc.

Princeton, NJ 08540

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